CASE 100-7664F/C5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
WALTER PRIKOSZOVICH
APPLICATION NO: Not Yet Assigned
FILED: Herewith
FOR: IMPROVEMENTS IN OR RELATING TO ORGANIC COMPOUNDS

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Kindly enter the following preliminary amendment prior to calculating the filing fee for the application.

IN THE SPECIFICATION

At page 1, after the title and before the first paragraph, please insert the following: -- This application is a continuation of U.S. Application 09/089,836, filed June 3, 1998, which is a continuation of U.S. Application 08/471,053, filed June 6, 1995, now Patent No. 5,795,593, issued August 18, 1998, which is a continuation of U.S. Application 08/353,467, filed December 9, 1994 which is a continuation of U.S. Application 08/121,674, field September 15, 1993, now abandoned, which is a continuation of U.S. Application 07/737,960, filed July 30, 1991, now abandoned.

IN THE CLAIMS

Please cancel claims 1 – 31.

Please add the following claims:

32. A polymer, which is off-white to white in color, and which polymer contains one or more metals in cationic form, the metal cation(s) having a concentration of at most 10 ppm, wherein the polymer is obtained through the process of purification comprising the steps of

- contacting a solution of an impure polymer with a matrix, and
- isolating the purified polymer from the solution.

33. A polymer, according to claim 32, wherein its off-white to white color is further defined by the requirements of the colour strengths of reference solutions B_2-B_9 of the brown colour test of the European Pharmacopeia, 2nd Edition (1980) part I, Section V, 6.2.

34. A polymer according to claim 33 wherein the purified polymer is a polylactide polymer.

35. A polymer according to claim 34 wherein the polylactide polymer is a polylactide co-glycolide polymer.

36. A polymer according to claim 35 wherein the polylactide co-glycolide polymer contains Sn++ ions as the cationic metal ion(s).

37. A polymer according to claim 36 wherein the polylactide co-glycolide polymer contains the Sn++ in a concentration of from about 1. To about 1.5 parts per million (ppm).

38. A polymer according to claim 32 wherein said metal ion has ethyl hexanoate as a corresponding salt anion.

39. A polymer according to claim 37 wherein the polylactide co-glycolide polymer is a polylactide co-glycolide having a mean molecular weight (Mw) of from 25,000 to 100,000 and a polydispersity ($Mw/_{Mn}$) of from 1.2 to 3.0.

40. A polymer according to claim 35 wherein the polylactide co-glycolide polymer is linear.

41. A polymer according to claim 40 wherein the linear polylactide co-glycolide polymer has a lactidal glycolide molar ratio of 100-25/0-75.

42. A polymer according to claim 40 wherein the linear polylactide co-glycolide polymer has a lactidal glycolide molar ratio of 75-25/25-75.

43. A polymer according to claim 40 wherein the linear polylactide co-glycolide polymer has a lactidal glycolide molar ratio of 60-40/40-60.

44. A polymer according to claim 35 wherein the polylactide co-glycolide polymer is star-shaped.

45. A polymer according to claim 44 wherein the star-shaped polylactide co-glycolide polymer is an ester of a polyol containing at least 3 hydroxyl groups.

46. A polymer obtained through the process according to claim 32, wherein said matrix has surface acidic groups.

47. A polymer obtained through the process according to claim 32, wherein said matrix has surface carboxylic groups.

48. A polymer obtained through the process according to claim 32, further including, contacting the solution of impure polymer with activated charcoal.

49. A polymer obtained through the process according to claim 32, wherein the matrix is activated charcoal.

50. A polymer obtained through the process according to claim 32, further including the step of ultrafiltration.

51. A polymer obtained through the process according to claim 32, wherein the polymer is dissolved in acetone.

52. A pharmaceutical composition containing a polymer, according to claim 32, as a matrix for a drug compound.

53. A pharmaceutical composition, according to claim 52, comprising bromocriptine as the drug compound.

54. A pharmaceutical composition, according to claim 52, comprising a peptide as the drug compound.

55. A pharmaceutical composition, according to claim 52, comprising somatostatin as the drug compound.

56. A pharmaceutical composition, according to claim 52, comprising octreotide, or an acid addition salt thereof, as the drug compound.

57. A process, for the preparation of the pharmaceutical composition of claim 52, which comprises combining the polymer of claim 32 with the drug compound to form an implantate or a microparticle.

REMARKS

This Preliminary Amendment adds the lineage of this case to the Specification. In addition, claims 1-31 are cancelled and new claims 32-57 are added. Support for newly added claims 32-57 may be found in the Specification.

Entry of this Preliminary Amendment is respectfully requested.

Respectfully submitted,

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